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09/806,795	04/04/2001	Staffan Folestad	1103326-0660	6487

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PATENT DEPARTMENT
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NEW YORK, NY 10036

EXAMINER

TSOY, ELENA

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,795

Applicant(s)

FOLESTAD ET AL.

Examiner

Elena Tsoy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 22-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Response to Amendment

1. Amendment filed on March 5, 2003 and Pre Amendment filed on June 24, 2002 have been entered. Claim 21 has been cancelled. New claims 42-53 have been added. Claims 1-20, 22-53 are pending in the application.

Claim Objections

2. Objection to claims 4-21, 23, 28-41 under 37 CFR 1.75(c) as being in improper form because a multiple dependency has been withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Rejection of claim 22 under 35 U.S.C. 101 because of the claimed recitation of a use, without setting forth any steps involved in the process resulting in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101 has been withdrawn.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Rejection of claims 1-3, 24-27 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention has been withdrawn.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **Claims 1-3, 7-9, 13-16, 20, 22-27, 31, 32, 37, 41, 47, 48, 53** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Drennen, III et al (US 5,750,996).

As to claims 1-3, 16, 20, 24-26, 31, 37, 41, 48, 53, Drennen, III et al disclose a method and apparatus for monitoring the formation of a coating on a single article such as drug unit (particle) (See column 2, lines 1-5; column 3, lines 44-48), comprising the steps of: arranging the particle at a given spatial location in a fluidized bed by fluidizing the particle on an upwardly directed flow (See Fig. 2; column 4, lines 36-38); forming said coating on the particle by spraying the particle with a coating material through nozzle (See column 3, lines 65-67); and monitoring on-line (continuously) (See column 2, lines 65-67; column 3, lines 60-62) by a near-infrared spectrometric measurement on said coating during said step of forming said coating to

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obtain a measurement value of at least once principle parameter related to said coating such as amount of coating or coating thickness (See Abstract; column 2, lines 55-60).

As to claim 7, 9, 13-15, 32, 47, an apparatus of Drennen, III et al provides not only nondestructive inspection of a coated article to determine the extent of coating, it also provides means for determining **other characteristics**, such as granulation, **drying**, mixing and potency in drug layering (See column 1, lines 66-67; column 2, lines 1-5). In operation, a **computer** will have stored information regarding the desired extent of coating such that, as will be known to those skilled in the art, a comparison between the actual measured extent of coating and the desired extent of coating may be made in a **quantitative** or **qualitative** basis (See column 6, lines 21-33). Microprocessor means (control unit) may be employed so as to control operation of the inspection means as by controlling delivery of near infrared light, operation of the spectrometer means and, if desired, use of the information obtained from inspection in a servomechanism concept to **adjust** or **halt the coating system** (control of a wetting period) (See Figs. 9, 10; column 2, lines 38-43).

As to claim 8, it is the Examiner's position that the computer has an aggregate model for prediction of the influence of the control parameter on the principal parameter for a large number of the particles based on the functional relationship for the single particle *inherently* since Drennen, III et al teach that the inspection can be made on a single coated particle (See column 5, lines 5-12).

As to claims 22, 23, Drennen, III et al do not expressly show whether coating is carried out continuously or in batch process. However, it is the Examiner's position that monitoring the coating formation can be done by spectrometer means in either process.

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As to claim 27, an apparatus of Drennen, III et al comprises air distribution plate in the lower region with a flow of air within the apparatus so that air will flow between the particle and a measurement unit (shielding gas) (See Fig. 1; column 4, lines 35-45).

10. **Claims 4-6, 28-30, 35, 36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Drennen, III et al (US 5,750,996) in view of Van Laethem (US 4,125,391).

Drennen, III et al, as applied above, fail to teach that the step of forming the coating on the particle includes generating a single droplet of a fluid, and bringing said droplet to impinge on said particle.

Van Laethem teaches that the use of a single droplet discharge head of small dimensions allows easy control of the rate of supply of a coating material (See column 2, lines 28-33).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a single droplet discharge head of small dimensions instead of spray nozzles in Drennen, III et al for supplying a coating material with the expectation of providing the desired easy control of the rate of supply of a coating material, as taught by Van Laethem.

11. **Claims 10, 33, 42-44, 50** are rejected under 35 U.S.C. 103(a) as being unpatentable over Drennen, III et al (US 5,750,996) in view of Cody (US 5,420,681).

Drennen, III et al, as applied above, fail to teach that the method comprises controlling property of the gas flow (Claims 10, 33, 42), such as a flow rate, a temperature or a content of a solvent (Claims 43, 44, 50).

Cody et al teach that pressure, temperature and net volume or mass flow are the normal way of monitoring the state of fluidization within a fluidized bed or while a unit is operating (See column 2, lines 27-30). It is the Examiner's position that mass flow depends on gas flow rate.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have monitored an inlet air temperature, a product temperature, a spray liquid temperature, a spray nozzle temperature, an atomizing air temperature, a spray liquid line temperature, a coating zone temperature, a fluidizing gas flow, and atomizing gas pressure in a method of Drennen, III et al for coating particles with the expectation of providing the desired normal coating operation since Cody et al teach that pressure, temperature and net volume or mass flow are the normal way of monitoring the state of fluidization within a fluidized bed or while a unit is operating.

12. **Claims 11, 17, 38, 45** are rejected under 35 U.S.C. 103(a) as being unpatentable over Drennen, III et al (US 5,750,996) in view of Maguire et al (US 6,038,525).

Drennen, III et al, as applied above, fail to teach that spectrometric measurement can be used to control property of the particle (Claim 11) such as size, shape, density, porosity (Claim 45), and is performed by a method based on Raman scattering (Claims 17, 38).

Maguire et al teach that Raman spectroscopy techniques may be used to monitor both the thickness and the chemical characteristics of a substrate (See column 4, lines 12-27).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used Raman spectroscopy techniques for monitoring a coating process of Drennen, III et al since Maguire et al teach that Raman spectroscopy techniques may be used to monitor both the thickness and the chemical characteristics of the film.

13. **Claims 12, 34, 46, 52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Drennen, III et al (US 5,750,996) in view of Van Laethem (US 4,125,391), as applied above, and further in view of Patel et al (US 6,248,363).

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Drennen, III et al in view of Van Laethem, as applied above, fail to teach that the method comprises controlling property of the droplet (Claims 12, 34), such as size, generation rate, or concentration of a constituent (Claims 46, 52).

Patel et al teach that some critical success parameters in a fluidized bed coating of particles such as bed temperature, atomization, atomization fluid temperature, or droplet size, spray type, spray rate, rate of coating droplet solidification on particle surfaces, particle size, shape, etc., can be readily adjusted by one skilled in the art to achieve a satisfactory product fluidized bed coating (See column 50, lines 44-52).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have controlled some critical success parameters in a fluidized bed coating of particles such as bed temperature, atomization, atomization fluid temperature, or droplet size, spray type, spray rate, rate of coating droplet solidification on particle surfaces, particle size, shape, etc. with the expectation of providing the desired satisfactory product fluidized bed coating, as taught by Patel et al.

14. **Claims 18, 39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Drennen, III et al (US 5,750,996) in view of Teuscher et al (US 5,091,278).

Drennen, III et al, as applied above, fail to teach that spectrometric measurement is performed by infrared spectrometry.

Teuscher et al teach that infrared spectrometer may be used for measuring the thickness (See column 14, lines 62-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used infrared spectrometry for monitoring a coating process of Drennen, III et

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al since Teuscher et al teaches that infrared spectrometer may be used for measuring the thickness.

15. **Claims 19, 40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Drennen, III et al (US 5,750,996) in view of Woodruff (US 5,420,681).

Drennen, III et al, as applied above, fail to teach that spectrometric measurement is performed by a method based on Raman scattering.

Woodruff teaches that imaging spectrometer may be used for measuring the thickness (See column 8, lines 15-17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used imaging spectrometer for monitoring a coating process of Drennen, III et al since Woodruff teaches that imaging spectrometer may be used for measuring the thickness.

16. **Claims 49, 51** are rejected under 35 U.S.C. 103(a) as being unpatentable over Drennen, III et al (US 5,750,996) in view of Van Laethem (US 4,125,391), as applied above, and further in view of Cody (US 5,420,681).

Drennen, III et al in view of Van Laethem, as applied above, fail to teach that the method comprises controlling property of the gas flow (Claim 49), such as a flow rate, a temperature or a content of a solvent (Claim 51).

Cody et al teach that pressure, temperature and net volume or mass flow are the normal way of monitoring the state of fluidization within a fluidized bed or while a unit is operating (See column 2, lines 27-30). It is the Examiner's position that mass flow depends on gas flow rate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have monitored an inlet air temperature, a product temperature, a spray liquid

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temperature, a spray nozzle temperature, an atomizing air temperature, a spray liquid line temperature, a coating zone temperature, a fluidizing gas flow, and atomizing gas pressure in a method of Drennen, III et al in view of Van Laethem for coating particles with the expectation of providing the desired normal coating operation since Cody et al teach that pressure, temperature and net volume or mass flow are the normal way of monitoring the state of fluidization within a fluidized bed or while a unit is operating.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy whose telephone number is (703) 605-1171. The examiner can normally be reached on 9:00-5:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive Beck can be reached on (703) 308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

ET

Elena Tsoy
Examiner
Art Unit 1762

April 28, 2003


MICHAEL BARR
PRIMARY EXAMINER